



Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

Convergent Dental Incorporated
% Ms. Carrie Hetrick
Emergo
816 Congress Avenue, Suite 1400
Austin, Texas 78701

September 23, 2015

Re: K151306
Trade/Device Name: Solea
Regulation Number: 21 CFR 878.4810
Regulation Name: Laser surgical instrument for use in general and
plastic surgery and in dermatology
Regulatory Class: Class II
Product Code: GEX
Dated: May 14, 2015
Received: May 18, 2015

Dear Ms. Hetrick:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the [Federal Register](#).

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-

related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to

<http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

Joshua C. Nipper -S

For Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)

K151306

Device Name

Solea

Indications for Use (Describe)

The Solea system is indicated for the following:

- Ablation of hard tissue for caries removal and cavity preparation
- Incision, Excision, Vaporization, Coagulation and Hemostasis of soft tissue in the oral cavity
- Cutting, shaving, contouring and resection of oral osseous tissue (bone)

Type of Use (Select one or both, as applicable)

Prescription Use (Part 21 CFR 801 Subpart D)

Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) (Signature)

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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510(k) Summary for Solea

1. Submission Sponsor

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2. Submission Correspondent

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3. Date Prepared

August 14, 2015

4. Device Identification

Trade/Proprietary Name: Solea
Common/Usual Name: Powered laser surgical instrument
Classification Name: Laser surgical instrument for use in general and plastic surgery
and dermatology
Classification Regulation: 21 CFR §878.4810
Product Code: GEX
Device Class: Class II
Classification Panel: General and Plastic Surgery

5. Legally Marketed Predicate Device(s)

Convergent Dental, Inc., Solea, 510(k) Numbers: K123494, K130420
Biolase Technology, Inc., Waterlase MD, 510(k) Number: K091746
Fotona d.d., LightWalker Laser System, 510(k) Number: K101817

6. Device Description

The Solea system is a dental laser device previously cleared by the FDA for soft tissue dental indications (K123494) and hard tissue indications (K130420). The only changes from the previously cleared device are the addition of the osseous tissue indications. There have been no software changes or graphic changes to the Solea system. The osseous tissue settings are the same as the previously cleared device (K130420). The osseous settings have substantially equivalent fluence and irradiation as the hard tissue predicate devices. There are no other hardware or software changes to the Solea system device pending herein when compared to the device cleared under K123494 and K130420.

The Solea system is a mobile, cart-based dental treatment system that uses pulsed laser energy to cut and ablate hard tissue and to cut soft tissue in the oral cavity. The Solea system utilizes advanced CO2 laser technology with a wavelength of 9.25 μ m to safely and effectively perform ablation, incision, excision, vaporization, coagulation and hemostasis procedures.

7. Indication for Use Statement

The Solea system is indicated for the following:

- Ablation of hard tissue for caries removal and cavity preparation
- Incision, Excision, Vaporization, Coagulation and Hemostasis of soft tissue in the oral cavity
- Cutting, shaving, contouring and resection of oral osseous tissue (bone)

8. Substantial Equivalence Discussion

The following table compares the Solea to the predicate devices with respect to intended use, technological characteristics and principles of operation, providing more detailed information regarding the basis for the determination of substantial equivalence.

The Convergent Dental, Inc. Solea system is a dental laser previously cleared by the FDA for hard tissue indications (K130420) and soft tissue indications (123494).

The Solea system included herein is the same device that was previously cleared by the FDA in K130420 (Solea, expanded hard tissue indications) and K123494 (Solea®, indications for soft tissue indications). There are no unique applications, indications, materials or specifications presented herein. All the presented indications for use retain the same meaning as their equivalent indications cleared by the FDA.

The subject Solea system is substantially equivalent to the Biolase Technology, Inc. Waterlase MD (K091746) and the Fotona d.d., LightWalker Laser System (K101817) for the osseous tissue indications in terms of fluence, irradiance, measured comparative performance data, and all features that affect safety or effectiveness.

The following table compares the subject Convergent Dental, Inc. Solea system to the Biolase Technology Inc. Waterlase MD, Fotona d.d. LightWalker Laser System Family, and the previously cleared Solea systems, with respect to intended use, technological characteristics and principles of operation, providing more detailed information regarding the basis for the determination of substantial equivalence for intended uses.

	Convergent Dental, Inc.	Convergent Dental, Inc.	Convergent Dental, Inc.	Biolase Technology, Inc.	Fotona d.d.
Trade Name	Solea	Solea	Solea	Waterlase® MD	LightWalker Laser System Family
510(k) Number	K152306	K130420	K123494	K091746	K101817
Common name	Powered Laser surgical instrument	Powered Laser surgical instrument	Powered Laser surgical instrument	Powered Laser surgical instrument	Powered Laser surgical instrument
FDA Classification Names	Powered Laser surgical instrument	Powered Laser surgical instrument	Powered Laser surgical instrument	Powered Laser surgical instrument Drill, bone, powered System, Dental, Hydrokinetic, Carries Removal & Cavity Preparation	Powered Laser surgical instrument
FDA Classification codes	GEX, a Class II device	GEX, a Class II device	GEX, a Class II device	GEX, MXF, DZI, a Class II device	GEX, a Class II device
Predicates cited	K130420 and K123494 for hard and soft tissue indications K091746, K101817 for osseous tissue indications	K091746, K101817 for hard tissue indications K123494 for soft tissue indications	K091320 for soft tissue indications	K031140, K071363, K090181 for hard tissue indications	K093162 for hard tissue indications
Target User	General practitioner dentists and specialists	General practitioner dentists and specialists	General practitioner dentists and specialists	General practitioner dentists and specialists	General practitioner dentists and specialists
Indications for Use	The Solea system is indicated for the following: - Ablation of hard tissue for caries removal and cavity preparation - Incision, Excision,	The Solea system is indicated for the following: - Ablation of hard tissue for caries removal and cavity preparation. - Incision, Excision,	The Solea system is indicated for the following: - Incision, Excision, Vaporization, Coagulation and Hemostasis of soft tissue in the oral cavity.	General Indications* Class I, II, III, IV and V cavity preparation Caries removal Hard tissue surface roughening or etching Enameloplasty, excavation of pits and fissures for placement of sealants* * For use on adult and	The LightWalker Er:YAG laser, and its accessories, are intended for use in dentistry, dermatology and other surgical areas in the following procedures: In dentistry, for: - Intra-oral soft tissue surgery (incision, excision,

	Convergent Dental, Inc.	Convergent Dental, Inc.	Convergent Dental, Inc.	Biolase Technology, Inc.	Fotona d.d.
	<p>Vaporization, Coagulation and Hemostasis of soft tissue in the oral cavity</p> <ul style="list-style-type: none"> - Cutting, shaving, contouring and resection of oral osseous tissue (bone) 	<p>Vaporization, Coagulation and Hemostasis of soft tissue in the oral cavity.</p>		<p>pediatric patients Root Canal Hard Tissue Indications Tooth preparation to obtain access to root canal Root canal preparation including enlargement Root canal debridement and cleaning Root Canal Disinfection Laser root canal disinfection after endodontic instrumentation Bone Surgical Indications Cutting, shaving, contouring and resection of oral osseous tissues (bone) Osteotomy Endodontic Surgery (Root Amputation) Indications Flap preparation – incision of soft tissue to prepare a flap and expose the bone. Cutting bone to prepare a window access to the apex (apices) of the root(s). Apicoectomy – amputation of the root end. Root end preparation for retrofill</p>	<p>ablation coagulation) - Leukoplakia - Pulpotomy as adjunct to root canal retreatment - Pulp extirpation - Removal of fibroma - Removal of granulated tissue - Caries removal, cavity preparation, enamel roughening - Sulcular debridement - Tooth preparation to obtain access to root canal, root canal debridement and cleaning, root canal preparation including enlargement - Cutting, shaving, contouring and resection of oral osseous tissue (bone) - Osteotomy,</p>

	Convergent Dental, Inc.	Convergent Dental, Inc.	Convergent Dental, Inc.	Biolase Technology, Inc.	Fotona d.d.
				<p>amalgam or composite. Removal of pathological tissues (i.e., cysts, neoplasm or abscess) and hyperplastic tissues (i.e., granulation tissue) from around the apex NOTE: Any tissue growth (i.e., cyst, neoplasm or other lesions) must be submitted to a qualified laboratory for histopathological evaluation. Soft Tissue Indications including Pulpal Tissues* Incision, excision, vaporization, ablation and coagulation of oral soft tissues, including: Excisional and incisional biopsies Exposure of unerupted teeth Fibroma removal Flap preparation – incision of soft tissue to prepare a flap and expose the bone. Flap preparation – incision of soft tissue to prepare a flap and expose unerupted teeth (hard and soft</p>	<p>osseous crown lengthening, osteoplasty - Apicectomy surgery.</p> <p>Removal of subgingival calculi in periodontal pockets with periodontitis by closed or open curettage</p>

	Convergent Dental, Inc.	Convergent Dental, Inc.	Convergent Dental, Inc.	Biolase Technology, Inc.	Fotona d.d.
				tissue impactions) Frenectomy and frenotomy Gingival troughing for crown impressions Gingivectomy Gingival incision and excision Hemostasis Implant recovery Incision and drainage of abscesses Laser soft tissue curettage of the post-extraction tooth sockets and the periapical area during apical surgery Leukoplakia Operculectomy Oral papillectomies Pulpotomy Pulp extirpation Pulpotomy as an adjunct to root canal therapy Root canal debridement and cleaning Reduction of gingival hypertrophy Removal of pathological tissues (i.e., cysts, neoplasm or abscess) and hyperplastic tissues (i.e., granulation tissue) from around the apex NOTE: Any tissue growth (i.e., cyst, neoplasm	

	Convergent Dental, Inc.	Convergent Dental, Inc.	Convergent Dental, Inc.	Biolase Technology, Inc.	Fotona d.d.
				<p>or other lesions) must be submitted to a qualified laboratory for histopathological evaluation. Soft tissue crown lengthening Treatment of canker sores, herpetic and aphthous ulcers of the oral mucosa Vestibuloplasty Laser Periodontal Procedures Full thickness flap Partial thickness flap Split thickness flap Laser soft tissue curettage Laser removal of diseased, infected, inflamed and necrosed soft tissue within the periodontal pocket Removal of highly inflamed edematous tissue affected by bacteria penetration of the pocket lining junctional epithelium Removal of granulation tissue from bony defects Sulcular debridement (removal of</p>	

	Convergent Dental, Inc.	Convergent Dental, Inc.	Convergent Dental, Inc.	Biolase Technology, Inc.	Fotona d.d.
				<p>diseased, infected, inflamed or necrosed soft tissue in the periodontal pocket to improve clinical indices including gingival index, gingival bleeding index, probe depth, attachment loss and tooth mobility) Osteoplasty and osseous recontouring (removal of bone to correct osseous defects and create physiologic osseous contours) Ostectomy (resection of bone to restore bony architecture, resection of bone for grafting, etc.) Osseous crown lengthening Laser assisted new attachment procedure (cementum-mediated periodontal ligament new-attachment to the root surface in the absence of long junctional epithelium). Removal of subgingival calculi in periodontal</p>	

	Convergent Dental, Inc.	Convergent Dental, Inc.	Convergent Dental, Inc.	Biolase Technology, Inc.	Fotona d.d.
				pockets with periodontitis by closed or open curettage.	
Laser classification	Class 4 (IV) Laser Product	Class 4 (IV) Laser Product	Class 4 (IV) Laser Product	Class 4 (IV) Laser Product	Class 4 (IV) Laser Product
Type of Laser	CO ₂ (Carbon Dioxide)	CO ₂ (Carbon Dioxide)	CO ₂ (Carbon Dioxide)	Er,Cr:YSGG (Erbium, Chromium: Yttrium, Scandium, Gallium, Garnet)	Er:YAG (Erbium: Yttrium, Aluminum, Garnet) Nd:YAG (Neodymium-doped: Yttrium, Aluminum, Garnet)
Wavelength	9.25µm (9250nm)	9.25µm (9250nm)	9.25µm (9250nm)	2.78µm (2780nm)	Er:YAG = 2.94µm (2940nm) Nd:YAG = 1.064µm (1064nm)
Fluence: Energy per mm²	0.39J/mm ² (hard tissue) 1.13J/mm ² (soft tissue)	0.39J/mm ² (hard tissue) 1.13J/mm ² (soft tissue)	1.13J/mm ²	0.33J/mm ²	0.25J/mm ²
Irradiance: Power per mm²	6W/mm ² (hard tissue) 112.8W/mm ² (soft tissue)	6W/mm ² (hard tissue) 112.8W/mm ² (soft tissue)	112.80W/mm ²	10W/mm ²	13W/mm ²
Operating Modes	Ablation laser: Pulsed Aiming laser: Continuous	Ablation laser: Pulsed Aiming laser: Continuous	Ablation laser: Pulsed Aiming laser: Continuous	Ablation laser: Pulsed Aiming laser: Continuous	Ablation laser: Pulsed Aiming laser: Continuous
Beam Delivery	Articulating Arm (Free Space)	Articulating Arm (Free Space)	Articulating Arm (Free Space)	Fiber	Articulating Arm (Free Space)
Sterilization Method	Steam Autoclave	Steam Autoclave	Steam Autoclave	Steam Autoclave	Steam Autoclave
RF emissions	CISPR 11 Group 1	CISPR 11 Group 1	CISPR 11 Group 1	CISPR 11 Group 1	CISPR 11 Group 1
EMC compliance	CISPR 11 Class A	CISPR 11 Class A	CISPR 11 Class A	CISPR 11 Class A	CISPR 11 Class A

9. Non-Clinical Testing

The Solea system meets all the requirements for overall design, sterilization, biocompatibility, and electrical safety. The results of the non-clinical testing confirm the output meets the design inputs and specifications. Bench testing was performed to

demonstrate substantial equivalence to the predicate devices in terms of safety and performance. The following non-clinical testing was performed:

- **Electrical Safety Testing:**
The system passed electrical safety testing in accordance with requirements for IEC 60601-1 medical electrical equipment.
- **Electromagnetic Compatibility:**
The system passed electromagnetic compatibility (EMC) testing to meet requirements for IEC 60601-1-2 medical electrical equipment.
- **Laser Safety:**
The system passed particular requirements for IEC 60601-2-22 and IEC 60825-1 for the safety of diagnostic and therapeutic laser equipment.
- **Cleaning and Sterilization:**
The handpieces of the Solea system passed cleaning and sterilization validations for reusable medical devices based on the overkill approach to demonstrate sterilization cycle lethality as described in AAMI TIR12 to achieve a Sterility Assurance Level (SAL) of at least 10^{-6} . The Solea system handpieces are designed for sterilization by exposure to moist heat under conventional autoclave cycles qualified to ANSI/AAMI ST79.
- **Software:**
Verification and validation testing was conducted on the Solea software. All tests were completed successfully with respect to stated pass/fail criteria thereby deeming the device and software appropriate for its intended use.
- **Usability:**
Usability testing was conducted on the Solea system as described in IEC 62366. During the usability evaluation, dentists used the system to perform procedures on simulated tissues in a laboratory environment that replicates the intended deployment environment of the dental office. Based on the participant feedback and ratings of usability of the Solea system, all of the acceptance criteria for the user design validation have been met for the intended use.
- **Bench Testing: Solea Hard Tissue Testing:**
Performance data was collected from Bench Testing for hard tissue. Results show that hard tissue thermal effects are equivalent. The results show substantially equivalent results for the Solea system and predicate systems.

10. Clinical Testing

There was no clinical testing required to support the medical device as the indications for use is equivalent to the predicate devices. These types of devices, including the predicate devices, have been on the market for many years have been on the market for many years with a proven safety and efficacy for the use of the device. The non-clinical testing detailed in this submission supports the substantial equivalence of the device.

11. Statement of Substantial Equivalence

By definition, a device is substantially equivalent to a predicate device when the device has the same intended use and the same technological characteristics as the previously cleared predicate device.

The Solea system has the same or similar intended use, indications, principles of operation,

and technological characteristics as the predicate devices. Solea, as designed and manufactured, is determined to be substantially equivalent to the referenced predicate devices in terms of intended use, design, materials, and function.